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#28

Robert A. Armitage
Vincent & Elkins LLP
Suite 700
1455 Pennsylvania Ave. NW
Washington DC 20004-1008

In Re: Patent Term Extension
Application for
U.S. Patent No. Re. 36,755

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. Re. 36,755 for a period of 230 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

RE: ENBREL® (etanercept)
FDA Docket No. : 99E-1086

Attention: Claudia Grillo

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : Re. 36,755
(45) ISSUED : June 27, 2000
(75) INVENTOR : Craig A. Smith, et al.
(73) PATENT OWNER : Immunex Corporation
(95) PRODUCT : ENBREL® (etanercept)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. Re. 36,755 based upon the regulatory review of the product ENBREL® (etanercept) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 230 days

from March 7, 2012, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 16th day of September 2004.

Jon W. Dudas

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office